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Health Policy Analysis

Pharmaceutical Policy Reforms to Regulate Drug Prices in the Asia Pacific Region: The Case of Australia, China, India, Malaysia, New Zealand, and South Korea

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ABSTRACT

Medicine price directly affects affordability and access to medicines particularly in countries where a major portion of pharmaceutical spending is through out-of-pocket payment, such as in the Asia Pacific region. We have undertaken a detailed appraisal of the pharmaceutical policy reforms to regulate drug prices in 3 developed (Australia, New Zealand, and South Korea) and 3 emerging (China, India, and Malaysia) economies of the Asia Pacific region. Despite continuous efforts by the authorities in adopting a wide range of reformatory pharmaceutical pricing policies to ensure affordability of medicines, these policies may not be optimal where drug prices were not lowered as expected (eg, in Korea). On the contrary, considerable price reductions of various pharmaceuticals have been observed in New Zealand and India because of the reform in pharmaceutical pricing policy. This review of pharmaceutical pricing reforms reinforces the need for constant monitoring by policy makers in Asia Pacific countries to regulate drug prices and to undertake reform in pharmaceutical pricing policies when necessary to ensure affordability and access to medicines.
Keywords: access, affordability, Asia, Pacific, pharmaceutical, policy, pricing..

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Introduction

Competition within the pharmaceutical market is limited because of information asymmetry and divided responsibility between the purchasing decision makers and the patients who bear the cost. Therefore, revision and reform of pharmaceutical pricing policy are needed to contain the unfair pricing of medicines in view of inadequate competition. This is especially true in countries with inadequately regulated pharmaceutical systems and improper price regulation allowing pharmaceutical manufacturers to set high prices for their products, benefiting from their monopolistic power and the relatively inelastic demand for medicine. Medicine prices directly affect affordability and access to medicines particularly in health systems in which a major portion of pharmaceutical spending is through out-of-pocket payment and the availability of medicines in publicly funded healthcare facilities is relatively low. The pharmaceutical markets in the Asia Pacific region demonstrate heterogeneity in pharmaceutical pricing mechanisms. We have undertaken a detailed appraisal of the pharmaceutical policy reforms to regulate drug prices in 3 developed (Australia, New Zealand, and South Korea) and 3 emerging (China, India, and Malaysia) economies of the Asia Pacific region.

Pharmaceutical Pricing Policies in Developed Economies

Australia

The Australian market of prescription drugs has undergone some transformation since 2001 with the entry of many generic medicines after patent protection expiry. A plethora of studies published in the subsequent few years reported higher prices of Australian generic medicines relative to other similar countries, with prices almost reaching the corresponding originator brands.[1,2] For example, 9 medicines listed on the Pharmaceutical Benefits Scheme (PBS) were found to be more expensive in Australia than in both New Zealand and the United Kingdom.[1]

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Moreover, a study comparing the prices (adjusted using purchasing power parity ratios) of 34 medicines in Australia with those in New Zealand, which included 12 medicines with generic versions available, showed that the Australians paid higher prices for 11 generic medicines than the New Zealanders, which registered a total cost difference of more than A$ 460 million.[2]

Rather than engaging in competitive discounting of drug prices to the government, the suppliers of generic medicines competed on offering low drug prices to the pharmacists. As a result, the government reimbursed the pharmacists at prices higher than what were actually paid.[3,4] To rectify the loopholes, the Australian government undertook some major reforms in the administration of PBS in August 2007, with modifications of the compensation arrangements between pharmacies and pharmaceutical wholesalers as well as in the pricing of PBS-listed medicines. This pricing policy reform commanded the creation of 2 separate formularies for PBS medicines, namely, F1 formulary and F2 formulary, as well as the introduction of price disclosure and statutory price reductions.

A second wave of the reforms was introduced by the Australian government in December 2010, with further price reductions for medicines listed on the F2 formulary and for first-time listed generic medicines.[5] Furthermore, the introduction of the Expanded and Accelerated Price Disclosure policy mandated price disclosure for every medicine listed on the F2 formulary and reduced the cycle for price disclosure from 24 months to 18 months.[5] As a result of this policy, 160 medicines had price reductions after price disclosures between April 2012 and August 2014, with an average price reduction of 42%.[5] The cycle has been further reduced to 12 months after the implementation of the Simplified Price Disclosure policy in October 2014, allowing PBS prices to be adjusted to market prices more quickly.[6]

Although the reform has been focusing on the market of generic medicines, concerns were being raised regarding the high prices of several new medicines negotiated by the pharmaceutical industry. Therefore, managed entry agreements have been implemented to allow access to some new medicines with specific cost-effective clinical indications, but with limited use outside of these clinical indications.[1] Some agreements are pricing arrangements where price or volume discount is in place, whereas other agreements are performance- or outcome-based, which require achieving certain clinical outcomes for continued reimbursement.

New Zealand

During the 1980s, the rise in drug prices was a major problem in New Zealand, where in some years, a growth rate as high as 20% was noted. This rise in drug prices crowded out other aspects of healthcare expenditure.[7] The Pharmaceutical Management Agency (PHARMAC) was established in June 1993 to manage the government's spending on medicines within the amount of available fund.

The creation of PHARMAC encouraged price competition among pharmaceutical manufacturers to drive drug prices down.[6,8,9] The reference pricing method was a significant strategy used in achieving price reductions, where the government reimbursement is fixed for all medicines within a therapeutic subgroup. This method compels the manufacturer to either match the reference price for a group of medicines or risk patients and prescribers selecting a different medicine because patients pay the additional cost if the actual price of a medicine is higher than the government reimbursement.[10] In addition, since 1997, PHARMAC has been tendering out sole supply contracts for generic medicines, for a limited period, to encourage the development of cheaper generic versions of off-patented medicines.[10] In fact, half of the total volume of reimbursed drugs is purchased through tenders.

Expenditure cap is one of PHARMAC's strategies for ensuring rebates where it acts as risk-sharing agreements to ensure that if the sales volume of a listed pharmaceutical exceeds an agreed-upon level, the pharmaceutical manufacturer is responsible for covering all or part of the additional costs.[11-13] With regard to cross-product (bundling) agreements, PHARMAC would negotiate a discount on the price of one or more of the currently listed pharmaceuticals provided by the pharmaceutical manufacturer who applies for a listing of a new pharmaceutical that is clinically effective but not cost-effective.[6,11,14]

PHARMAC started to assume the role of operating the financial budget for inpatient pharmaceuticals within the district health boards (DHBs) after the introduction of the National Hospital Pharmaceutical Strategy in 2002, allowing each DHB to make its own inpatient pharmaceutical formulary decisions and to administer its own budget for inpatient pharmaceuticals.[15] This change, however, raised concerns regarding inequities in access on the basis of where a patient lived (sometimes referred to as postcode lottery). In July 2013, PHARMAC replaced all DHB pharmaceutical formularies with a nationwide inpatient pharmaceutical formulary, namely, the Hospital Medicines List.[15]

Considerable savings have been achieved for several medicines because of PHARMAC's reformatory efforts over the years, with the price of statins, for instance, reducing to about half the price that they were in Australia.[16] An analysis undertaken by the Canadian government also reported that the price of generic drugs in New Zealand was less than a quarter of that in Canada.[17] In addition, the patented drugs were about 10% cheaper in New Zealand compared with Canada.[18]

South Korea

In South Korea, after the introduction of the National Health Insurance System (NHIS) in 2000, the prices of reimbursed drugs are being regulated. Drugs available only with prescriptions are mostly being reimbursed, and their prices are controlled by the Maximum Allowable Price (MAP) policy.[19] Nevertheless, for non-reimbursable drugs, pharmaceutical manufacturers and retail pharmacies could independently set their prices.

The MAP policy, which has come into effect along with the introduction of the NHIS, sets an upper limit of remuneration or a ceiling price for pharmaceutical products that are being reimbursed. For newly introduced innovator medicines, their MAPs were determined on the basis of cross-country price comparison (external reference pricing), for which the average wholesale prices of the innovator medicines in selected industrialized countries were considered as the international comparator. Nevertheless, this pricing mechanism was criticized as potentially contributing to escalating drug prices because all the 7 comparator countries have larger and stronger economies than South Korea.[20-22]

There were, however, some substantial changes in the pricing mechanisms after the enactment of the Pharmaceutical Expenditure Rationalization Plan in 2006 and the single price system in 2012, in view of the mounting opinion pleading to drive the drug prices down to make them affordable for Korean consumers. With the introduction of the Pharmaceutical Expenditure Rationalization Plan, which is a comprehensive pharmaceutical regulation package, the application for drug reimbursement operates with a positive list system whereby the Health Insurance Review and Assessment Service would compare the cost effectiveness of the candidate innovator product with the most frequently used alternative, which could be a drug or a medical procedure, when pharmaceutical manufacturers file a listing application.[23] The MAP for a candidate product could be set without any form of agreement other than pricing adjustments by the Benefit

Coordination Committee if the candidate product contains one or more of the essential medicines.

The introduction of the single price system aims to encourage market competition by taking advantage of low-cost generic medicines. The core principle of this policy is based on the internal reference pricing method, where the same MAP was set for both the innovator brand and its generic versions of a particular medicine. With the promulgation of the single price system, prices for the immediate off-patent innovator products would be reduced to 70% of the prices before the expiry of the patent. In addition, the Korean Linkage Price System for the pricing of generic products has been abolished, and instead generic products would be priced at 85% of the prices of their corresponding immediate off-patent innovator products (equivalent to 59.5% of the prices before the expiry of the patent), irrespective of the order of market entry.[22,23] One year after the expiry of the patent, the off-patent innovator products and their generic counterparts would then be uniformly priced at 53.55% of the prices of the innovator products before the expiry of the patent.

Nevertheless, Kwon et al[24] examined whether the aim of the single price system to encourage market competition by setting the same MAP for both generic and innovator products was achieved. It was observed that despite a decrement in market shares of the innovator products, which was only marginal, their market shares remained high, with innovator products being prescribed about 6 times more than the generic versions after the introduction of the new policy. Moreover, price dispersion was narrowed rather than being broadened, indicating that the prices of generic products were not lowered as expected. The results suggest that there was no market competition, which could be due to a lack of coordination between demand- and supply-side policies as hypothesized by the authors, because demand-side measures to promote increased prescribing and dispensing of the low-cost generic products were not implemented along with supply-side price-cutting policies.

Pharmaceutical Pricing Policies in Emerging Economies

China

Historically, in China, the Bureau of Pricing under the National Development and Reform Commission (NDRC) was responsible for the pricing of all drugs and medical devices listed on the drug formulary for reimbursement under publicly funded medical insurance programs, at the national as well as provincial levels. There were 2 categories to the drug formulary, namely, category A and category B. The maximum retail prices of category A drugs, which were definitive ceilings for retail pharmacies and public hospitals, were determined by the NDRC at the national level. Prices were set for each active ingredient and dosage form on the basis of declared costs by manufacturers multiplying by some markups to account for profits as well as costs of research and development. For drugs in category B, although their guiding prices were set by the NDRC at the national level, the price ceilings were determined by the governments at the provincial level, usually established through a local tendering system.

Over the years, there has been a large body of evidence suggesting that price ceilings have been ineffective in containing drug prices. One study that determined the effect of 4 price ceilings on the cost of antibiotics in 12 hospitals between 1996 and 2005 in Beijing, China, reported more than a quadruple increase in the overall expenditure on antibiotics although the prices of targeted antibiotics were 47% less in 2005 than in 1996.[25] The authors hypothesized that prescribers could evade price ceilings easily by substitution with more expensive antibiotics or prescribing higher doses of antibiotics.[25] Similarly, in another study that considered macroeconomic data to determine the effects of price regulations, it was found that despite a small initial decrement in pharmaceutical price indicators, the regulations did not cut household spending on pharmaceuticals or the profitability of pharmaceutical firms.[26] In fact, price regulations indirectly caused an increase in the importation of more expensive foreign-manufactured medicinal products.[26]

In 2015, China introduced a series of legislative and policy reforms to relax the administrative controls over drug prices in which the price ceiling policies have been formally abolished.[27] The reforms were introduced to build a system whereby pharmaceutical prices are mainly determined as a result of orderly market competition rather than regulation by the authorities.[27] The core component of the reforms is the abolishment of the classification system of drugs into categories A and B and the introduction of new mechanisms of price control. With the newly announced policy, drug pricing control, formerly the primary responsibility of the NDRC, would be shared by the Ministry of Human Resources and Social Security and the National Health and Family Planning Commission.[27,28] The NDRC has introduced a reimbursement standard to function as a guide for the market prices of pharmaceuticals included in the formulary for which there is an existing market competition.[27,28] It is understood as a form of a reference price used in internal reference pricing systems.[27,28] Although NDRC's Academy of Macroeconomic Research suggests that drug quality, drug costs, and winning tender prices could be incorporated into the definition of reimbursement standard, there was no conclusive guidance provided.[28] Therefore, Chinese local administrative divisions have the autonomy to use their own methodology before the introduction of final regulations at the national level.[29] The formulary medicines with little or no market competition (ie, in-patent drugs) are not included in the reimbursement standard system. For these products, retail prices would be established by a multilateral and transparent negotiation mechanism involving the pharmaceutical industry and other stakeholders.[29]

India

Pharmaceutical pricing policies have been introduced formally in India since 1963 with the promulgation of the Drugs (Display of Prices) Order of 1962 and the Drugs (Control of Prices) Order of 1963 under the Defence of India Rules, where the drug prices were frozen after the waging of war with China.[30] Thereafter, a series of price control regimes were notified through various orders that varied in the extent and the nature of control of drug prices.[30]

When the Drugs (Prices Control) Order of 1966 came into effect, the government was not legitimized to reduce the prices of pharmaceuticals, although prior approval from the government was required for increasing the prices of certain drugs. The enactment of the Drugs (Prices Control) Order of 1970 had legitimized the right for the government to set the price ceilings of bulk drugs for the first time, for which the price ceilings of 18 bulk drugs were revised, whereas the prices of other bulk drugs were frozen with no increment allowed without prior approval from the government.[30] Nevertheless, since the promulgation of the Drugs (Prices Control) Order of 1979, a selective approach was undertaken where only scheduled bulk drugs and their pharmaceutical formulations were brought under a price control ambit. The Drugs (Prices Control) Order of 1995 constituted a major departure from the previous policies on the selection of scheduled drugs for price control.

A pharmaceutical pricing policy, announced in the year 2002, aimed to further relax the control over drug pricing with a proposal to liberalize the economic criteria for the listing of drugs under price control, including the market share and the limit of turnover of drugs.[30] Nevertheless, the new policy was challenged

in the court, which eventually hindered its implementation and the government was ordered by the Supreme Court to devise relevant criteria to ensure the application of price control on essential, lifesaving drugs.

Taking the court order into consideration, the National Pharmaceuticals Pricing Policy was introduced after much deliberation in the year 2012,[30] which proposed 3 key changes that constituted a radical departure from the then-existing drug price control policy: drugs that come within the ambit of price control would be decided on their essentiality instead of economic criteria, bulk drugs would no longer come within the ambit of price control, and market-based pricing mechanism instead of cost-based pricing mechanism would be used to determine and regulate the prices of finished pharmaceutical formulations. The Drugs (Prices Control) Order of 2013 had been introduced to implement the 2012 National Pharmaceuticals Pricing Policy with some important provisions in line with the policy, including fixing of the ceiling price of every drug with finished pharmaceutical formulations specified in the National List of Essential Medicines (NLEM) on the basis of data obtained from market research. The ceiling price for a certain finished pharmaceutical formulation is the average of the prices of available brands with market share of at least 1%, and annual revision is allowed on the basis of the variations in the Wholesale Price Index.[31] In addition, approval by the government is needed for the pricing of innovator drugs, new strengths of existing drugs, and combinations of existing drugs, considering the rational basis of experts' recommendations.

Since the introduction of the Drugs (Prices Control) Order of 2013, prices for many drugs have declined dramatically, with price reductions of 84.2% for ofloxacin 200-mg tablets, 65.8% for omeprazole 20-mg capsules, 56.5% for azithromycin 500-mg tablets, 47.6% for amlodipine 2.5-mg tablets, 36% for atorvastatin 10-mg tablets, and 21.1% for sodium valproate 500-mg tablets.[31] In addition, the ceiling prices of more than 100 finished pharmaceutical formulations of drugs not included in the NLEM or the other strengths of drugs specified in the NLEM were revised by the National Pharmaceutical Pricing Authority of India in July 2014. The revision covered 50 cardiovascular and antidiabetic medicines, upon observing the hike in prices for drugs not included in the NLEM by more than 25% of the simple average.[32]

Malaysia

The Ministry of Health of Malaysia, which serves as the largest healthcare service provider within the Malaysian public healthcare sector, controls the medicines within the public healthcare sector at prices lower than those within the private healthcare sector by formulating and administering the Ministry of Health Medicines Formulary since 1983. The formulary includes every pharmaceutical formulation approved by the Drug List Review Panel to be reimbursed by the government and made available for the healthcare facilities within the public healthcare sector.[33]

The private healthcare sector practices an open market economy concept and a price deregulation system where the medicine prices are wholly dependent on the prevailing market forces without an external control (ie, pharmaceutical-free market).[34] Over the years, because of free pricing policy, escalation of drug prices has been observed in Malaysia in the published literature. Malaysia has been known as a "high price island" for pharmaceutical prices. A study conducted by Babar et al[34] between 2004 and 2005 reported that the generic brand and innovator brand medicines were on average priced 6 times and 16 times higher, respectively, than the international reference prices in the community pharmacies. In line with what has been observed earlier, in 2012, Hassali et al[35] compared the mean retail prices of medicines in the state of Penang, Malaysia, with the corresponding prices in Australia and reported that the prices were 30.3% to 148.2% higher in Malaysia.

In view of the observed high drug prices, the Pharmaceutical Service Division of the Ministry of Health has undertaken a few initiatives. The Medicine Price Unit has been set up by the Pharmaceutical Service Division tasked to monitor the trends of medicine prices in Malaysia, and the unit operates in accordance with the concept outlined in the Malaysian National Medicines Policy by the Malaysian government to "ensure equitable access and rational use of safe, effective and affordable essential medicines of good quality."[36,37] A national database on the information of medicine prices has subsequently been developed by the Medicine Price Unit to enhance the implementation of the Malaysian National Medicines Policy with regard to containment of medicine price, ensuring accessibility and affordability of medicines, and provision of actual drug pricing scenario. In addition, the Pharmaceutical Service Division was directly involved in the monitoring of markups of medicines to check the rising medicine prices.[34] Furthermore, guidelines on "Good Pharmaceutical Trade Practice (GPTP)" have been issued by the Pharmaceutical Service Division, although without mandatory effect, which aim to encourage fair trade practices among different players in the private healthcare sector, namely, private hospitals, community pharmacies, and general practitioners' clinics.[37] It is detailed within the GPTP that all pharmaceutical distribution channels in the private healthcare sector should be offered similar incentive schemes for the purchased pharmaceuticals.[38] Nevertheless, the GPTP received opposition from some pharmaceutical industry stakeholders who preferred to maintain the existing free market status.[38]

Discussion

It is worth noting that considerable price reductions of various pharmaceuticals have been observed in New Zealand because of pharmaceutical policy reforms. PHARMAC, which acts as a monopsony pharmaceutical purchaser in New Zealand, demonstrated that it is possible to manage drug spending within a capped public budget while improving access to subsidized medicines. Among the developed countries reviewed, New Zealand is the only country undertaking competitive tendering to obtain lower drug prices, whereas the others are using statutory legal processes to reduce the prices of pharmaceuticals. Nevertheless, it remains a concern that some of the pricing policies adopted by PHARMAC, such as grouping patented medicines with generics within therapeutic subgroups, discourage innovation.[6]

Australian drug prices remain high albeit the introduction of several pharmaceutical policy reforms. According to a recent report,[39] drug prices in Australia were 3.6 times higher than those observed in New Zealand. Although the price disclosure policy that was introduced in Australia in a bid to cut the prices of generic drugs has worked, it has not gone far enough or fast enough to achieve considerable savings to the government.[39] It has been proposed that the price disclosure policy should be supplemented by a more effective policy of benchmarking Australian drug prices to the prices paid by comparable countries, especially those of New Zealand.[39] Despite that, credit must be given to the Australian government for the implementation of managed entry agreements to reimburse and subsequently allow wider patient access to new medicines.[40] As a result of these risk-sharing agreements, the new molecular entities reimbursed in Australia were found to be more than double of those in New Zealand.[41] There is still much work to be done by the South Korean authorities despite constant revision of the pricing policy. The Korean NHIS fails to achieve the potential savings from the availability of low-cost medicines with the promulgation of the single price system.

In China, several components of the new drug pricing reform, especially the reimbursement standard, remain unspecified,

although it is likely to involve internal reference pricing policies as adopted in the member countries of the Organisation for Economic Co-operation and Development.[42] The implementation of internal reference pricing policies has raised some concerns because it promotes the use of cheap and low-quality drugs because a reliable quality control system is yet to be established.[40]

India is renowned for its strict price controls, especially those of essential medicines. Hard-line position and a nonrestrictive attitude toward the development of generic drugs for the domestic market—sometimes before the expiry of the patent protection period—have transformed India's generics industry into one of the world's foremost providers of low-cost medicines. Nevertheless, these policies have, to a certain extent, eroded the incentive of big pharmaceutical companies and international trade partners to invest in the Indian pharmaceutical market. The Indian authorities should seek to transform the market into one in which drug prices are kept low by competition among pharmaceutical manufacturers in the future, given that most drugs in India have sufficient volumes or market shares and are facing intense competition.[43]

Malaysia has a relatively weak pharmaceutical system among the countries reviewed, whereby pharmaceutical manufacturers could easily seize upon the relatively inelastic demand and their monopolistic power to set drug prices at high levels. The country should first empower the Pharmaceutical Service Division or other relevant authorities to enforce all the proposed price control policies, especially on the regulation of distribution chain markups and retail chain markups and fees (community pharmacies, private hospitals, and general practitioners' clinics), because they are always deemed as the contributors to the astronomical drug prices.[37]

One of the common themes surrounding pharmaceutical pricing policies among emerging economies in the Asia Pacific region, including the 3 emerging countries we have reviewed, is the absence of a formal and rigorous health technology assessment (HTA) program to inform the decision-making process about reimbursement of health technologies.[44] In contrast, HTA has found a firm footing in developed countries throughout the world, with variations in HTA and reimbursement processes among countries.[45,46] It is recommended that the next wave of pricing reforms encompass the implementation of formal HTA programs particularly in countries where an efficient allocation of limited health resources is needed.

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